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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,621	02/28/2002	Fong-Fong Chu	1954-397	3955

6449 7590 10/21/2002

ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/084,621

Applicant(s)

CHU ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, 40-49, and 60-63, drawn to a transgenic double knockout animal whose genome comprises a homozygous disruption of the endogenous Gpx1 gene and a homozygous disruption of the endogenous Gpx2 gene, cell obtained from said animal and a method of screening for potential therapeutic agents for the treatment of cancer using the same mouse, classified in classes 800, 800, 800 and 435, subclasses 13, 18, 3, and 325.
- II. Claims 26-34, drawn to a transgenic double knockout animal whose genome comprises a homozygous disruption of the endogenous Gpx1 gene and a homozygous disruption of the endogenous Gpx2 gene wherein the animal further comprises a nucleotide sequence encoding a protein of interest, and a method of assessing the therapeutic effect of a heterologous gene of interest on the development of cancer, classified in classes 800, subclass 13.
- III. Claims 35-39, drawn to a method of identifying markers associated with cancer by assessing the absence or level of expression of the gene or protein, classified in classes 435 and 435, subclasses 6 and 7.1.

- IV. Claims 50-51, and 58-59, drawn to a method for selecting an agent for treating a metabolic disorder comprising screening agents in a transgenic double knockout mouse whose genome comprises a homozygous disruption of the endogenous Gpx1 gene and a homozygous disruption of the endogenous Gpx2 gene, classified in class 800, subclass 3.
- V. Claims 52-57 and 65 drawn to a method of selecting an agent that modulates GPX enzyme activity in isolated mouse cells, classified in classes 435 and 435, subclasses 7.2 and 7.21.
- VI. Claim 64, drawn to isolated mammalian cells comprising homozygous disruptions in both the Gpx1 and Gpx2 genes, classified in class 435, subclass 325.
- VII. Claim 66, drawn to a method of selecting an agent for treating a metabolic disorder comprising screening said agents in isolated Gpx1 and Gpx2 knockout cells, classified in class 435, subclass 4.

Inventions III, IV, V and VII are distinct each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods that have different uses and different modes of operation and different functions and also require materially different reagents for practice. For example, the screening method of Group III is used for identifying cancer markers, the screening method of Group IV

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requires the use of a transgenic non-human animal and is directed to screening agents that can treat a metabolic disorder, the screening method Group V is directed to screening agents that modulate GPX enzyme activity in isolated mouse cells, and the screening method of Group VII is used to screen for agents, in isolated mouse cells, that can treat a metabolic disorder. The different screening methods of Groups III, IV, V, and VII appear to require different classes of candidate agents for practice as the claimed methods comprise different methods with different goals. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement and different classification, restriction for examination purposes as indicated is proper.

Inventions I, II, and VI are distinct each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are products that have different uses, different functions, and different effects. For example, the transgenic non-human animal of Group I can be used as a model of disease, the transgenic non-human animal of Group II is structurally different from the transgenic non-human animal of Group I because it comprises a different, additional transgene and presumably has a different phenotype, and the isolated cells of Group VI can be used to produce a protein. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

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matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions III, IV, V, VII and I, II, VI are distinct each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The products of Groups I, II, and VI can be used in materially different methods from the methods of Groups III, IV, V and VII. The methods of Groups III, IV, V, and VII can be practiced with materially different products that have different chemical structures from the products of Groups I, II, and VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 308-0009.

Peter Paras, Jr.

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*Pete Paras Jr*  
*Art Unit 1632*